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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,263	10/10/2000	Noah Syroid	4314 P	5909

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EXAMINER

AHMED, AAMER S

ART UNIT PAPER NUMBER

3763

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/686,263	<b>Applicant(s)</b> SYROID ET AL.	
	<b>Examiner</b> Aamer S. Ahmed	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 649 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/24/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 8-10, and 12-19, 22-30, 35, 36 and 41-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson U.S. Patent Number 5,088,981 in view of Johnson et al U.S. Patent Number 5,522,798.

Howson et al ('981) discloses a system for data representation comprising a drug delivery system (52, 54) a data stream device (50) in communication with the drug delivery device system (52, 54) and a drug delivery display monitor (28), in communication with a data stream device (50), see figures 1 and 2. Furthermore, Howson et al ('981) discloses that the drug delivery system comprises a simulator, which simulates bolus, infusion and anesthetic drug administration (col. 4 line 3). Moreover, Howson et al ('981) discloses a drug display monitor

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(28) comprising a data decoder (20) receiving data from the data stream device (50); a dosage calculator (32) receiving decoded data from the data decoder; a drug modeler (26) and normalizer (24) receiving calculated data from the data decoder; a storage device (16), receiving drug and dosage data from the drug modeler and normalizer; and a display generator (28), wherein the display generator produces a display of more than one drug dosages, drug name, past, present and predicted drug site concentration and effect site concentration in three-dimensional form and a system for data representation comprising a processor (16), computing drug models, producing an internal representation of drug display data and decoding a data stream; a memory unit in communication with the processor; a graphics adapter (24c) in communication with the processor and a display monitor in communication with the graphics adapter, see figures 1 and 2 and col. 13, 14 and 15.

Howson et al fails to explicitly disclose that the drug monitor is configured to depict past, predicted and real-time drug concentrations. Johnson et al discloses similar device, which graphically depicted past, predicted and real-time drug concentrations (col. 17. line 44 and col. 12 line 9). Moreover, Johnson et al teaches that the display monitor is configured to depict a percent likelihood that the at least one drug has a desired effect based on results from a predefined population that is at least ninety-five percent of the population and wherein a plurality of inputs includes the height and weight of the subject (see col. 15 line 60).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Howson et al by incorporating the graphical drug concentration display of the type taught by Johnson et al in order to give the physician

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information in evaluating the need for changes in the desired drug concentration set point (col. 17 line 49).

Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al ('981) in view of Teeple Jr. U.S. Patent Number 5,925,014. Howson et al ('981) discloses the drug delivery system as described above in reference to claim 6 and further comprising an infusion pump (14 see col. 10 line 13). Howson et al ('981) fails to disclose an anesthetic administration machine and one or more bar coded syringes. Teeple Jr. discloses an anesthetic administration machine (30 see figure 3); and one or more bar coded syringes (31-33 see figure 3). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the drug delivery system of Howson et al ('981) by incorporating anesthesia administration and bar coded syringes as taught by Teeple Jr. ('014) in order to insure that the proper drug mix is achieved, reducing if not eliminating the possibility for human error (Teeple Jr. col. 4 line 67).

Claims 20, 21, 31-34 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howson et al in view of Johnson et al and further in view of Teeple Jr. Howson and Johnson disclose the device as described above, but fail to explicitly disclose that the components are sedative, neuromuscular blocker and analgesic (col. 10 line 27 and col. 1 line 19).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device Howson in view of Johnson by adding the sedative, analgesic

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and neuromuscular agents as taught by Teeple Jr. in order to make a more effective drug delivery system.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 7 and 9-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 7-11 and 15 of copending Application No. 10/269422. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 8 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 8 and 19 of copending Application No. 10/269422 in view of Johnson et al U.S. Patent Number 5,522,798.

Howson et al fails to explicitly disclose that the drug monitor is configured to depict past, predicted and real-time drug concentrations. Johnson et al discloses similar device, which does graphically depicted past, predicted and real-time drug concentrations (col. 17. line 44 and col. 12 line 9). Moreover, Johnson et al teaches that the display monitor is configured to depict a percent likelihood that the at least one drug has a desired effect based on results from a predefined population that is at least ninety-five percent of the population and wherein a plurality of inputs includes the height and weight of the subject (see col. 15 line 60).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Howson et al by incorporating the graphical drug concentration display of the type taught by Johnson et al in order to give the physician information in evaluating the need for changes in the desired drug concentration set point (col. 17 line 49).

This is a provisional obviousness-type double patenting rejection.

### ***Response to Arguments***

Applicant's arguments with respect to claims 6-40 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed

  
